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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,000

Applicant(s)

WONG ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,36,47,48,52,59-62 and 69-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35, 36, 47, 48, 52, 59-62, and 69-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Claims 35, 36, 47, 48, 52, 59-62, and 69-71 are pending and under consideration in the application.
2. Because this action raises issues not raised in the prior action, it is made Non-Final.

Priority

3. It is noted that the Applicant has argued that the present application has priority to two U.S. provisional applications, 60/107,507, and 60/109,409. However, the Applicant is not accorded priority to these applications because the Applicant has not met the requirements for such a claim under 35 U.S.C. 119(e), or 37 CFR 1.78 (a)(2). In particular, the reference to these applications was not submitted within the time frame described in 37 CFR 1.78(a)(2)(ii).

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. **(Prior Rejection- Maintained)** Claims 47 and 48 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims read on non-human primates, purposefully infected with the virus of claim 36. The Applicant has

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amended the claims to require that the primates be experimentally housed, and that the mammal is infected with a purified virus, and argues that these amendments distinguish over the naturally occurring animal. The arguments are not found persuasive. As was indicated in the prior action, there is no structural distinction between animals purposefully infected with the indicated virus or animals infected in nature. The Applicant has also failed to establish any structural distinction between animals infected with a purified virus and those in nature. Either animal is still a primate infected by the virus. Thus, the insertion of the term purified into the claim does not distinguish over the naturally occurring animals.

The Applicant also argues that animals found in nature are not experimentally housed. It is first noted that there has been no clear definition provided for the term “experimentally housed.” Thus, for the purposes of this action, the phrase is being treated as including any man-made structure. The Desrosiers article (of record in the Feb 2002 IDS) indicates that even animals in experimental conditions are subject to non-intentionally inflicted diseases. Thus, it is clear that even experimentally housed animals become naturally infected by pathogens that infect the primates in nature. Therefore, housing an animal in experimental housing does not distinguish from animals that may become naturally infected with the virus. Because the virus naturally infects primates both in the wild and in experimental housing, the Applicant’s amendment and arguments with respect to the experimental housing clause are not found persuasive.

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6. **(Prior Rejection- Withdrawn)** Claims 59-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The rejection of these claims is withdrawn in view of the amendment thereof.

Claim Objections

7. **(Prior Objection- Withdrawn)** Claim 35 was objected to because of the following informalities: The claim reads on an “isolated virus (RRV)...” The claim refers to RRV by its acronym without first identifying the virus by its complete name (Rhesus rhadinovirus). The objection is withdrawn in view of the amendment of the claim.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(Prior Rejection- Withdrawn)** Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is withdrawn in view of the amendment to the claim.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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11. **(Prior Rejection-Withdrawn)** Claims 35-37, 47, 48, 52, and 59-62 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Applicants arguments in traversal regarding pending claims 36, 47, 48, 52, and 59-62 are persuasive. The cancellation of claim 37 is noted. The rejection against each of these claims is therefore withdrawn. Claim 35 refers to the deposited material. The Applicant asserts that the ATCC statement submitted as exhibit A with the Response provides the assurances required by the Office. In view of this document, which indicates that the deposited material will be made available upon issuance of a U.S. Patent citing the strain, the rejection is withdrawn.

12. **(Prior Rejection- Maintained)** Claims 36, 37, 47-48, and 59-62 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for viruses, and methods of using viruses, comprising the genome of SEQ ID NO: 1, does not reasonably provide enablement for the claimed inventions wherein the virus comprises variants, even conservative variants, of the virus. Claim 37 has been cancelled from the application. Claim 36 has been amended to require that the virus comprises the nucleic acid of SEQ ID NO: 1 or a sequence at least 95% identical to SEQ ID NO: 1. New claims 70 and 71 require that the virus comprises a sequence, respectively, at least 95 and 98% identical to SEQ ID NO: 1. The rejection is maintained against claims 36, 47, 48, 59-62, and extended to claims 52, 70, and 71.

The Applicant traverses the rejection by asserting that the Applicant was in possession of variants to SEQ ID NO: 1, and that those in the art would be capable of making and using virus with variants of SEQ ID NO: 1. The Applicant also asserts that examples of variants have been

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disclosed on pages 24-25, and 55-56 of the application. These arguments are not found persuasive.

The Examiner agrees that those in the art would be readily able to construct modified virus based on the disclosure presented by the Applicant. However, while those in the art would be able to make such virus, absent further information or experimentation they would not be able to determine what effects an particular variation to the genome sequence would have on the activity of the virus. Even limiting the claims to embodiments with 95% or 98% identity, in view of the genome length of over 130,000 nucleotides, this still allows for over 2600 individual variations from the sequence of SEQ ID NO: 1. While the Applicant presented, on pages 55-56, examples of certain related proteins that may be made for comparison to determine a limited number of variations to the sequence that may be made, such does not provide sufficient information to enable those in the art to make and use nucleic acids to the full extent as claimed.

As was indicated above, the claims still cover a broad range of potential virus and viral genomes. Further, as was described in the prior action, there is notable unpredictability in the art of protein modification, and thus in the art relevant to a viral genome encoding viral proteins. In view of the limited information and guidance as to operable variants provided by the application, the broad scope of the claims, the lack of working examples, and the unpredictability in the art, the Applicant has not provided sufficient information such that those in the art could readily and reliably eliminate inoperative variants without undue experimentation. For the reasons above, and the reasons of record, the rejection is maintained.

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13. **(New Rejection)** Claims 36, 47, 48, 52, 59-62, 70, and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been described above. The cover a genus of viral genomes comprising variants of SEQ ID NO: 1 such that virus comprising such genomes would be capable of infecting and causing lymphadenopathy in immunocompromised primates.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed. However, the presence of multiple species within a claimed genus does not demonstrate possession of the genus in every situation. See, *In re Smyth*, 178 U.S.P.Q. 279 at 284-85 (CCPA 1973) (stating "where there is

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unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application.”); and University of California v. Eli Lilly and Co., 43 USPQ2d 1398, at 1405 (Fed Cir 1997)(citing Smyth for support).

In the present case, the Applicant has neither provided examples of operable variants to the genome that are illustrative of the entire genus being claimed, nor provided teachings as to what functions and structures in the viral genome are required for the performance of the claimed function (i.e. there is no correlation made between known structures and the claimed function). In view of the lack of examples, and the lack of teachings regarding what modifications may be made to the viral genome without a loss of function, and in view of the unpredictability regarding what variants would be able to perform the claimed functions, the Applicant has not provided an adequate written description to support the full scope of the claimed genus.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. **(Prior Rejection-Maintained)** Claims 35-37 were rejected under 35 U.S.C. 102(a) as being anticipated by Searles et al. (J Virol 73: 3040-53). These claims read on isolated RRV comprising the genome of SEQ ID NO: 1. The Applicant traverses the rejection on the grounds

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that the present application claims priority to two provisional applications, which disclose the claimed virus, and which predate the indicated reference. However, while the Examiner agrees that, were the Applicant to be afforded priority of these applications the rejection would be overcome, as was described above in this action, the Applicant has not met the conditions under 37 CFR 1.78 to be entitled to such priority. The rejection is therefore maintained against pending claims 35 and 36, and extended to new claims 69-71.

Claim Rejections - 35 USC § 103

16. **(Prior Rejections- Withdrawn)** Claim 49 was rejected under 35 U.S.C. 103(a) as obvious over Mahairas et al. (Genbank Accession number AQ622034), or unpatentable over any of Derosiers et al., Genbank Accession AF029302; Berthomme et al., Accession L24487; Accession AF087411; or Davison et al. (J Gen Virol 67: 1759-1816). These rejections are withdrawn in view of the cancellation of the claim. .

Conclusion

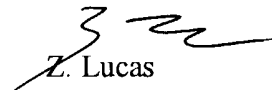
17. No claims are allowed.


18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


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